

## §§ 405.2100—405.2101

## 42 CFR Ch. IV (10–1–11 Edition)

not be considered in any appeal of the revised determination or decision.

[73 FR 30266, May 23, 2008]

### Subparts S–T [Reserved]

### Subpart U—Conditions for Coverage of Suppliers of End-Stage Renal Disease (ESRD) Services

AUTHORITY: Secs. 1102, 1861, 1862(a), 1871, 1874, and 1881 of the Social Security Act (42 U.S.C. 1302, 1320b–8, 1395x, 1395y(a), 1395hh, 1395kk, and 1395rr), unless otherwise noted.

SOURCE: 41 FR 22511, June 3, 1976, unless otherwise noted. Redesignated at 42 FR 52826, Sept. 30, 1977.

#### §§ 405.2100—405.2101 [Reserved]

#### § 405.2102 Definitions.

As used in this subpart, the following definitions apply:

*Agreement.* A written document executed between an ESRD facility and another facility in which the other facility agrees to assume responsibility for furnishing specified services to patients and for obtaining reimbursement for those services.

*Arrangement.* A written document executed between an ESRD facility and another facility in which the other facility agrees to furnish specified services to patients but the ESRD facility retains responsibility for those services and for obtaining reimbursement for them.

*Dialysis.* A process by which dissolved substances are removed from a patient's body by diffusion from one fluid compartment to another across a semipermeable membrane. The two types of dialysis that are currently in common use are hemodialysis and peritoneal dialysis.

*End-Stage Renal Disease (ESRD).* That stage of renal impairment that appears irreversible and permanent, and requires a regular course of dialysis or kidney transplantation to maintain life.

*ESRD facility.* A facility which is approved to furnish at least one specific ESRD service (see definition of “ESRD service”). Such facilities are:

(a) *Renal dialysis center.* A hospital unit which is approved to furnish the full spectrum of diagnostic, therapeutic, and rehabilitative services required for the care of ESRD dialysis patients (including inpatient dialysis furnished directly or under arrangement). A hospital need not provide renal transplantation to qualify as a renal dialysis center.

(b) *Renal dialysis facility.* A unit which is approved to furnish dialysis service(s) directly to ESRD patients.

(c) *Self-dialysis unit.* A unit that is part of an approved renal transplantation center, renal dialysis center, or renal dialysis facility, and furnishes self-dialysis services.

(d) *Special purpose renal dialysis facility.* A renal dialysis facility which is approved under § 405.2164 to furnish dialysis at special locations on a short-term basis to a group of dialysis patients otherwise unable to obtain treatment in the geographical area. The special locations must be either special rehabilitative (including vacation) locations serving ESRD patients temporarily residing there, or locations in need of ESRD facilities under emergency circumstances.

*ESRD Network organization.* The administrative governing body to the network and liaison to the Federal government.

*ESRD service.* The type of care or services furnished to an ESRD patient. Such types of care are:

(a) *Dialysis service*—(1) *Inpatient dialysis.* Dialysis which, because of medical necessity, is furnished to an ESRD patient on a temporary inpatient basis in a hospital;

(2) *Outpatient dialysis.* Dialysis furnished on an outpatient basis at a renal dialysis center or facility. Outpatient dialysis includes:

(i) *Staff-assisted dialysis.* Dialysis performed by the staff of the center or facility.

(ii) *Self-dialysis.* Dialysis performed, with little or no professional assistance, by an ESRD patient who has completed an appropriate course of training.

(3) *Home dialysis.* Dialysis performed by an appropriately trained patient at home.